Exhibit 1

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NOTE: UNPUBLISHED OPINION, SEE RCWA 2.06.040

Court of Appeals of Washington,
Division 1.
Mark E. DUXBURY, Appellant,
v.
ORTHO BIOTECH, INC. and Ortho Biotech Products, L.P., Respondents.
No. 52348-1-I.

May 3, 2004.

Appeal from Superior Court of King County; Hon. Bruce W. Hilyer.

Paul Eugene Simmerly, Attorney at Law, Bellevue, WA, for Appellant.

Daniel W. Ferm, Williams, Kastner & Gibbs PLLC, Rashelle C. Tanner, Crista Ministries, Sheryl Denise Johnso Willert, Attorney at Law, Seattle, WA, for Respondents.

UNPUBLISHED OPINION

ELLINGTON, J.

*1 A claim of wrongful discharge in violation of public policy must be supported by evidence that the dismissal was caused by conduct linked to public policy. Mark Duxbury contends that in 1995, he gave truthful testimony in a deposition, the testimony proved damaging to his employer, and in 1998, he was terminated as a result. The record does not establish a question of fact about that causal connection. We affirm summary judgment of dismissal.

FACTS

Background

Amgen, Inc. is the manufacturer of epoetin alfa, a drug that stimulates production of red blood cells in patients with chronic renal failure. In the early 1980s, Amgen granted an exclusive license to Ortho Biotech, Inc. to market epoetin alfa under the brand name Procrit. In the United States, Ortho was authorized to market Procrit only for use with non-dialysis patients; Amgen retained exclusive rights to market the drug for treatment of dialysis patients. Amgen markets the drug as Epogen.

The product license agreement contained an arbitration provision, and proceedings have apparently been ongoing on various issues since 1989. During the early 1990s, Ortho allegedly violated its product license agreement with Amgen by marketing Procrit for treatment of dialysis patients, and in 1993, Amgen sought to terminate its agreement with Ortho.

Arbitration proceedings on this issue lasted more than seven years. Eventually, Amgen was awarded $150 million in damages against Ortho. In related litigation, wholesale drug distributor Charise Charles, Ltd. filed suit against Amgen in Florida, after Amgen halted sales of Epogen to Charise Charles on grounds Charise Charles aided Ortho in violating the product license agreement by selling Procrit to independent dialysis centers.

Duxbury's Employment

Mark Duxbury was hired by Ortho as a product specialist (sales representative) in 1992. In this position, and later as a key account specialist, Duxbury was responsible for marketing Procrit in the Northwest. Between 1992 and 1994, Duxbury maintained an exemplary sales record and received several awards. His administrative skills, however, were in the 'needs improvement' category.

In August 1995, Duxbury and several other Ortho employees were subpoenaed to testify in the litigation between Amgen and Charise Charles.

In April 1996, Duxbury's supervisor, Michael Barton, was asked to investigate complaints that Duxbury had engaged in inappropriate, sexist behavior. Barton concluded there were 'some real issues here,' [FN1] and designed a training program for Duxbury. At around the same time, in a work session to evaluate Barton's leadership skills as district manager, Barton's supervisor suggested he fire Duxbury. Barton refused. Soon afterward, Barton was demoted; he later left the company. Barton later testified his demotion and departure had nothing to do with his refusal to fire Duxbury.

FN1. Clerk's Papers at 1113.

In October, 1996, Duxbury was directed to correct his last four expense reports. A new supervisor, Keith Wood, gave Duxbury a 'needs improvement' rating overall. Wood described Duxbury's administrative and organizational skills as 'unacceptable.' [FN2] Soon thereafter, Wood and Duxbury were refused entry at a client medical center. Wood issued Duxbury a written warning for that and other performance problems, including continued noncompliance with company policies concerning expense and activity reports.

FN2. Clerk's Papers at 538.

***2** Duxbury's next supervisor, John Woodhouse, notified Duxbury in April 1998 of numerous deficiencies in his performance, particularly in administrative areas, and enumerated eight areas in which Duxbury was required to improve by the time of his performance review at the end of June. A month later, Woodhouse wrote Duxbury that his failure to properly organize a promotional event was unacceptable. Duxbury's sales performance had also fallen, and Woodhouse set goals for improvement over the next few months. Although he disputes certain details, Duxbury admits his administrative skills were a continuing problem. He denies that his sales were significantly below average.

In mid-July, 1998, a regular customer, Western Washington Cancer Center, informed Woodhouse that Duxbury was no longer welcome on the premises because of repeated sexual and racial comments. The client also described administrative difficulties with Duxbury's handling of its account. Duxbury disputes the details of this complaint, but admits he told a 'Viagra' joke, and that the client's representative was offended. Several days later, Duxbury resigned in lieu of termination. [FN3]

FN3. The record contains evidence regarding personal pressures on Duxbury during these years. It serves no purpose to recite that evidence here.

Duxbury's Testimony

As indicated above, Duxbury was subpoenaed to testify in the Charise Charles lawsuit in 1995. Following his termination, Duxbury contacted Amgen, and provided testimony about Ortho's business practices on several occasions. He gave a second deposition in the Charise Charles suit in December 1998, depositions in the Amgen/Ortho arbitration in August and October, 2001, and testified in the arbitration hearing in January, 2002.

Wrongful Termination Suit

Duxbury filed this suit against Ortho in July, 2001, alleging wrongful discharge, breach of contract, tort of outrage, and infliction of emotional distress. Following discovery, Duxbury moved for partial summary judgment on several issues, and Ortho moved for summary judgment of dismissal. The court denied Duxbury's motion, granted Ortho's motion, and dismissed Duxbury's claims. Duxbury appeals. [FN4]

FN4. Duxbury does not address tort of outrage or contract issues in his brief on appeal. As to infliction of distress, he asserts only that emotional distress damages are recoverable in an action for wrongful termination. We therefore address only the merits of the wrongful termination claim.

DISCUSSION

Preliminary Rulings

Protective Order. Discovery in this case included Ortho's internal personnel files and communications, corporate business records, proprietary product information, and materials from the ongoing Amgen/Ortho arbitration, which were themselves subject to a protective order. Duxbury refused to stipulate to a similar order, and asserted his right to provide information to federal regulators or to the media. On Ortho's motion, the court entered a protective order:

> Any documents produced by either party in this action which are, in good faith, determined by the producing party to contain confidential or proprietary information, including without limitation, personally sensitive information of a non-public nature, may be designated as confidential, and so marked. [FN5]

FN5. Clerk's Papers at 173.

Under the order, documents designated as confidential were not to be disclosed except to the parties and their counsel, and were to be filed under seal; any party could seek to remove the confidentiality designation of a particular document or seek to modify the order.

*3 Duxbury contends the protective order was not justified under CR 26(c), that the documents submitted by Ortho did not contain trade secrets or other confidential information, and that the order was unduly restrictive as to the use of documents during depositions. Given the nature of the discovery, we see no error in the order. If Duxbury believed Ortho lacked a good faith basis for protecting a particular document, he had the right to seek a ruling on the document. He did not. He also had the right to seek a modification of the order. He never did. Further, he offers no argument that the protective order prejudiced his case.

When Duxbury violated the protective order by filing documents without placing them under seal, the court imposed $2,600 in sanctions. When Ortho later committed the same violation, Duxbury sought similar sanctions against Ortho. The court explained its reasoning for denying the motion:

> The protective order in this case was issued at the request of, ... and to protect the interests of, defendants. Given the history of this case, it is apparent to the court that this motion is intended to offset the sanctions previously ordered against plaintiff rather than to protect any legitimate interest of the plaintiff. The appropriate remedy for this violation of the court's order is that defendants, who were given notice and had a reasonable opportunity to cure their failure to take advantage of an order entered at their request, lose the order's protection regarding those documents previously filed that were not sealed. [FN6]

FN6. *Id.* at 1789-90.

These were tenable grounds for denying Duxbury's motion for sanctions. The court did not abuse its discretion.

Order Striking Declaration Content. Ortho moved to strike portions of declarations submitted by Duxbury during the summary judgment exchange. The court granted the motion. The stricken materials included portions of Duxbury's declaration in opposition to summary judgment, the entirety of Duxbury's declaration in strict reply to Ortho's response to his motion for partial summary judgment, and portions of the declarations of former Ortho employees Tom Fedorka, Renee Matson, and Oliver Medlock. For the most part, material was stricken as speculative, conclusory, argumentative, hearsay, or not within the declarant's personal knowledge.

Duxbury contends the declarants had personal knowledge. For example, regarding his own recitation of a witness's testimony in the arbitration proceedings, he argues, 'Certainly Duxbury could have witnessed or read Ms. Webb's testimony.' [FN7] Similarly, he contends he can recite the contents of pleadings and rulings in the arbitration because he has read them. Even information arguably within a declarant's personal knowledge, however, must be supported by a sufficient foundation, [FN8] and no such foundation appears in the declarations themselves. Duxbury contends Ortho should have addressed the issue by way of voir dire of the declarants. But showing a sufficient foundation is the burden of the proponent of evidence. [FN9] Ortho has no obligation to create a foundation for Duxbury's evidence, and in any case, Duxbury does not explain how Ortho would voir dire an affidavit submitted on summary judgment.

FN7. Brief of Appellant at 27-30.

FN8. ER 602.

FN9. See CR 56(e) (declarations opposing summary judgment must be made upon personal knowledge and must show the declarant's competence to testify to the contents).

*4 We have reviewed the record. The stricken portions of Duxbury's declarations contain numerous assertions that are hearsay, speculation, argument, and/or lack any foundation. [FN10] The same is true of the other stricken material. The court did not abuse its discretion.

FN10. Duxbury's own declarations describe documents, testimony given and statements made by others, ascribe motives and knowledge to others, and make arguments.

Wrongful Discharge Claim

The gravamen of this action is Duxbury's contention that he was discharged in retaliation for testifying, and that such a discharge violated public policy. A discharge is wrongful and gives rise to a tort action if it contravenes a clear mandate of public policy. [FN11] The cause of action has four elements: (1) existence of a clear public policy; (2) proof that discouraging the conduct in which the plaintiff engaged would jeopardize the public policy; (3) proof that the public policy-linked conduct caused the employee's dismissal; and (4) the absence of an

overriding justification for the dismissal. [FN12] The public policy exception to at-will employment is construed narrowly to guard against frivolous lawsuits . [FN13] What qualifies as a clear mandate of public policy is a question of law. [FN14]

FN11. *Thompson v. St. Regis Paper Co.*, 102 Wn.2d 219, 232, 685 P . 2d 1081 (1984).

FN12. *Gardner v. Loomis Armored, Inc.*, 128 Wn.2d 931, 941, 913 P . 2d 377 (1996).

FN13. *Id.* at 936 (citing *Thompson*, 102 Wn.2d at 232).

FN14. *Thompson*, 102 Wn.2d at 232.

Wrongful discharge actions have generally been allowed in four situations:

'(1) where employees are fired for refusing to commit an illegal act; (2) where employees are fired for performing a public duty or obligation, such as serving jury duty; (3) where employees are fired for exercising a legal right or privilege, such as filing workers' compensation claims; and (4) where employees are fired in retaliation for reporting employer misconduct, i.e., whistleblowing.' [FN15]

FN15. *Gardner*, 128 Wn.2d at 936 (citing *Dicomes v. State*, 113 Wn.2d 612, 618, 782 P.2d 1002 (1989)).

Duxbury alleges that in response to the 1995 deposition subpoena in the Charise Charles case, he testified truthfully, and Ortho fired him in 1998 because of that testimony. [FN16] Essentially, he argues that responding to a subpoena is a public duty, and that if an employee must suffer threat of discharge in retaliation for giving truthful testimony, a strong public policy is jeopardized. [FN17]

FN16. Duxbury also contends that, pursuant to subpoena, he provided documents adverse to Ortho, and that these documents were another reason for his termination. So far as we can ascertain, the summary judgment record does not contain those documents. Duxbury asserts they were attached to his (unverified) complaint, which is in the record on appeal. The documents describe a deliberate effort to market Procrit in the dialysis market. Duxbury states he supplied documents not to Charise Charles, but to Ortho's attorneys, and that he was not asked about them in the 1995 deposition.

FN17. Duxbury also contends his testimony was protected as 'whistleblowing.' But reporting a private contract violation is not whistleblowing. See *Dicomes v. State*, 113 Wn.2d 612, 618, 782 P .2d 1002 (1989) (no whistleblower protection where conduct reported not unlawful); *Wlasiuk v. Whirlpool Corp.*, 81 Wn.App. 163, 179, 914 P.2d 102 (1996) (same).

In general, we agree with this proposition. In *Blinka v. Washington State Bar Association*, [FN18] we recognized that 'CR 45 and the laws against perjury provide the foundation for a public policy prohibiting adverse employment action for responding to a subpoena or refusing to give false testimony.' Assuming this is so, however, the question is whether Duxbury has presented evidence suggesting his testimony was the cause of his discharge.

FN18. 109 Wn.App. 575, 585, 36 P.2d 1094 (2001), *review denied,* 146 Wn.2d 575 (2002).

Duxbury testified in 1995. He was not fired until 1998. Lack of proximity in time between the activity for which an employee alleges he was discharged, and the time of termination, indicates a lack of causal nexus. [FN19]

FN19. *Francom v. Costco Wholesale Corp.*, 98 Wn.App. 845, 862-63, 991 P.2d 1182 (2000); *Wilmot v. Kaiser Aluminum*, 118 Wn.2d 46, 69, 821 P.2d 18 (1991).

Duxbury explains this time lapse by pointing out that the Amgen/Ortho litigation took seven years. He argues that the significance of his testimony in the Amgen/Charise Charles litigation may not have been recognized by Ortho until later in the multi-million dollar Amgen/Ortho case, at which point the company sought to distance itself from testimony of disgruntled employees. Eventually, he argues, Ortho 'had to get rid of Mr. Duxbury' or appear to be 'endorsing his testimony.' [FN20]

FN20. Brief of Appellant at 19.

*5 The summary judgment record does not support this theory. We have only four pages from Duxbury's 1995 deposition. In that excerpt, he testified that a doctor at a kidney center, who was planning to purchase Procrit for use with dialysis patients, asked

Duxbury whether there was any difference between Procrit and Epogen for purposes of 'reimbursability.' [FN21] Duxbury testified he told the doctor it was his understanding that because the drug is the same, the federal government makes no distinction between the two products, so Procrit was eligible for reimbursement regardless of its use.

FN21. Clerk's Papers at 501.

Duxbury further testified he was aware of Ortho's 'absolutely strict' position that the dialysis market was 'out-of-bounds,' and that his manager was 'adamant' that Procrit was not to be promoted for dialysis use ('This was a big topic of conversation.'). [FN22] Duxbury stated he was nervous about admitting to his manager that he had been in a dialysis facility, 'except for the fact that there were non-dialysis patients being treated there.' [FN23]

FN22. *Id.*

FN23. *Id.*

Marketing for non-dialysis use was Duxbury's job, and the conversation he described does not indicate Ortho was marketing Procrit for dialysis patients. A physician with both non-dialysis and dialysis patients would presumably know the same drug was marketed under different names for each population and might reasonably be expected to ask questions, or even to ignore the licensing agreement. Nothing in the 1995 testimony is obviously harmful to Ortho.

Duxbury has several times stated as much. In later depositions in the Amgen arbitration, he said: 'I don't believe my {1995} testimony was damaging.' [FN24] He stated he had no reason to believe that Ortho was unhappy with his 1995 testimony, and said 'I don't think that I said anything that was particularly damaging to the company.' [FN25] Asked why he believed the 1995 deposition was the cause of his termination, he said that just the fact he 'was deposed at all was a problem,' [FN26] and that the timing of later events led him to believe his termination was connected to the deposition.

FN24. *Id.* at 90.

FN25. *Id.* at 809.

FN26. *Id.*

In his declaration in opposition to summary judgment below, however, Duxbury gives a markedly different description of his 1995 deposition. He declares he testified to a direct violation of the license agreement: to wit, that at his manager's request, he solicited dialysis business from clients who used Procrit almost exclusively for dialysis patients, and witnessed accounting practices designed to disguise these sales. Duxbury claims his 1995 testimony was similar to his later testimony in the Ortho/Amgen arbitration.

If so, it is difficult to see how Duxbury could have repeatedly described his 1995 testimony as not damaging. And if so, it is a mystery why Duxbury did not supply that part of his 1995 testimony for the record in this case, because the excerpt we have does not say what Duxbury now describes. Instead, it contradicts what he describes. In the excerpt before us, Duxbury emphasized his manager's strict insistence on compliance with the licensing agreement, and he neither stated nor implied that his manager directed him to violate the license agreement or set up reimbursement accounts to disguise such violations. [FN27] And finally, if the 1995 testimony was as Duxbury now describes it, he does not explain why Ortho needed three years to realize its damaging nature.

FN27. In a declaration submitted in opposition to Ortho's protective order, Duxbury gave further details of violations of the license agreement. According to Duxbury, Charise Charles received substantial discounts on purchases of Procrit, which it passed on to its customers in the form of reimbursements, thereby creating a competitive edge for Ortho's Procrit compared to Amgen's dialysis product, Epogen. Charise Charles made a practice of setting up billing accounts in the name of the physician, rather than the care center, to avoid creating records of sales to dialysis centers. Duxbury declares that at the direction of his manager, he set up an account for the physician he mentioned in the 1995 deposition, carefully following instructions from Charise Charles personnel. Duxbury states the physician used Procrit to treat both dialysis and non-dialysis patients, and received a substantial rebate from Ortho. When this came to light in the Amgen/Ortho litigation, it 'became extremely damaging.' Clerk's Papers at 142. This declaration was not part of the summary judgment record.

*6 Duxbury nonetheless contends his 1995 testimony was ultimately damaging to Ortho. As evidence of this, he points out that in the Amgen/Ortho litigation, Amgen sought to use certain depositions from the Amgen/Charise Charles case, among them his own, from 1995. [FN28] He also points to the fact that he later gave testimony adverse to Ortho in the Amgen/Ortho litigation, pointing to Ortho's post-arbitration submission of proposed findings.

FN28. Duxbury claims this motion was granted. It was not.

The motion papers supplied to us do not reveal the contents of the excerpt of the 1995 deposition Amgen later sought to use, and Duxbury has not supplied any record of his later testimony. But the proposed arbitration findings are in our record. Ortho proposed findings that several 'former disgruntled Ortho sales representatives' testified that Ortho had an unwritten policy to promote Procrit for dialysis, but that these witnesses all reaffirmed that Ortho's policy was to prohibit marketing for dialysis, and that none pointed to a single instance where Ortho directed them to promote Procrit for dialysis. [FN29] The proposed findings also state that 'at the direction of his manager, Mark Duxbury promoted Procrit to the nephrologist-owner of {a dialysis center}, but Duxbury acknowledged that the nephrologist also had pre-dialysis patients.' [FN30]

FN29. Clerk's Papers at 969-71.

FN30. *Id.* at 970.

Given the function of proposed findings, it is likely that Duxbury's testimony in the Amgen arbitration was at least as harmful to Ortho as Ortho's proposed findings suggest. At some point, therefore, it appears Duxbury did testify his manager directed him to promote Procrit in a way that would violate the agreement. [FN31]

FN31. The record does not contain the license agreement.

But that testimony was given long after Duxbury was fired. His 1995 testimony was not to the same effect. The damaging nature of the later testimony does not establish the damaging nature of the 1995 testimony. To establish a causal connection and overcome the three year lapse, Duxbury had to show a basis for a reasonable inference of causational nexus. If, as he now says, his 1995 testimony was obviously damaging, the three-year lapse cannot be explained. If, in the alternative, the damaging nature of his testimony was only later realized, Duxbury must show some basis for the connection between this realization and his termination. He does not.

The record is remarkable mainly for what is missing: obviously damaging content in the 1995 deposition; the absence of any of the later testimony; and the absence of any evidence that might explain why Ortho would wait three years before retaliating against Duxbury for his testimony pursuant to the 1995 subpoena.

Duxbury disputes many of Ortho's complaints about his performance. But he does not dispute engaging in gravely inappropriate behavior that offended a major client. He does not dispute consistently poor performance of administrative duties. And he repeatedly denied his 1995 testimony was damaging. Duxbury points to no evidence suggesting a nexus between that testimony and his termination in 1998, and the inferences he urges upon us are so attenuated as to amount to speculation. [FN32]

FN32. While Duxbury does not directly argue he was fired because Ortho feared he might be subpoenaed again and might then 'spill the beans,' we note such a theory is equally speculative. If Duxbury's description of Ortho's practices is accurate, Ortho had a similar motive to fire a large number of employees nationwide. Yet according to the record, only three of Ortho's seven 'disgruntled former employees' had been fired (including Duxbury).

*7 In sum, the record is insufficient to raise a question of fact that Duxbury was terminated in 1998 in retaliation for his testimony in 1995. The trial court did not err in granting summary judgment. [FN33]

FN33. Duxbury contends the trial court erred in denying his motion for partial summary judgment eliminating certain factual matters from trial. Specifically, Duxbury asked the court to rule that (1) his sales performance while at Ortho always exceeded the regional average, such that at trial, Ortho should not be allowed to refer to Duxbury's sales performance in any negative way; (2) Duxbury never committed an act of sexual or racial harassment or misconduct while employed by Ortho; (3) Michael

Barton was directed to terminate Duxbury in April 1996; and (4) the criticisms of John Woodhouse about an event Duxbury helped organize were fabricated. Assuming Duxbury had submitted sufficient evidence of causation, these were contested fact issues. Given our disposition on appeal, the issues are moot.

Not Reported in P.3d, 121 Wash.App. 1030, 2004 WL 938588 (Wash.App. Div. 1)

END OF DOCUMENT

Exhibit 2

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *ex rel.*, MARK EUGENE DUXBURY, Relators,	NO.
v.	Civil Action:
ORTHO BIOTECH PRODUCTS, L.P., Defendant.	**Filed in Camera Under Seal**

COMPLAINT

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false statements and claims made and presented by the defendant and/or its agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, as amended ("The Act"). The violations of the Act involve claims for reimbursement that defendant caused physicians and health care providers to submit which defendant knew were false and exaggerated. In violation of defendant's duty to report known errors resulting in unwarranted federal payments, defendant likewise concealed such errors from Government agents in order to keep funds to which they were not entitled.

2. The Act provides that any person who knowingly submits or causes to be submitted a false or fraudulent claim to the Government for payment or approval is liable for a civil penalty of up to $10,000.00 for each such claim submitted or paid, plus three times the amount of the damages sustained by the Government. Liability attaches both when a defendant

knowingly seeks payment that is unwarranted from the Government and when false records or statements are knowingly created or caused to be used to conceal, avoid or decrease an obligation to pay or transmit money to the Government. The Act allows any person having information regarding a false or fraudulent claim against the Government to bring an action for himself (the "Relator") and for the Government and to share in any recovery. The Complaint is filed under seal for 60 days (without service on the defendant during that period) to enable the Government: (a) to conduct its own investigation without the defendant's knowledge, and (b) to determine whether to join the action.

3. Specifically this action arises from false claims made for Medicare reimbursement for the use of the drug Procrit in the treatment of Medicare patients. In order to increase the market share of Procrit, defendant systematically employed devices that were in effect kickbacks in return for use of Procrit by the provider. Such a *quid pro quo* violates the anti-kickback statutes. Having secured the business of the provider, defendant caused the provider to make a claim for reimbursement.

4. Further, defendant also caused to be filed false claims in that defendant supplied health care providers with grants, rebates and other items of value in connection with the purchase of Procrit. Such items of value were not reflected in the Average Wholesale Price ("AWP") for Procrit as reported for reimbursement purposes by Medicare. Thus, the reported AWP was not the true AWP, which was at all times substantially less. This in turn caused Medicare to overpay for reimbursement.

II. PARTIES

5. The Relator, Mark Eugene Duxbury, (the "Relator"), resides at Milton, Washington.

6. Defendant Ortho Biotech Products, L.P., is believed to be a New Jersey limited partnership doing business in this District.

III. JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, which specifically confers jurisdiction on this Court of actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

8. This Court has personal jurisdiction over defendant pursuant to 31 U.S.C. § 3732(a), which provides that "[a]ny action under § 3730 may be brought in any judicial district in which the defendant, or in the case of multiple defendants, any one defendant can be found, resides, transacts business or in which any act proscribed by § 3729 occurred. Section 3732(a) also authorizes nationwide service of process. Defendant during the relevant period transacted business in this District.

9. As required under the False Claims Act, 31 U.S.C. § 3730(a)(2), the Relator has provided the Attorney General of the United States and the United States Attorney for the District of Massachusetts with a statement of all material evidence and information related to the Complaint. This Disclosure Statement supports the existence of over-charging Medicaid and Medicare for Procrit and the reliance by the United States government on invoices for said pharmaceutical product.

10. This Court has jurisdiction over this matter pursuant to 31 U.S.C. § 3730(b) in that the claims for relief in this action are brought in the name of the United States government.

11. Venue is proper pursuant to 28 U.S.C. § 1391(a) in that defendant does business within this judicial district.

IV. FACTUAL BACKGROUND

A. Ortho Commits AWP Fraud to Increase Market Share For Drugs Covered by Medicare Part B

1. The Medicare Insurance Program

12. In 1965, Congress enacted Title XVIII of the Social Security Act ("Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care.

13. The United States Department of Health & Human Services ("HHS") is responsible for the funding, administration and supervision of the Medicare Program. The Centers for Medicare and Medicaid Services ("CMMS"), formerly known as the Health Care Financing Administration ("HCFA"), is a division of HHS and is directly responsible for the administration of the Medicare Program.

14. The Medicare Program generally does not cover the cost of prescription drugs that a Medicare beneficiary self administers (*e.g.*, by swallowing the drug in liquid or pill form). However, Medicare Part B does cover some drugs, including injectables administered directly by a doctor, certain oral anti-cancer drugs, and drugs furnished under a durable medical equipment benefit. Approximately 450 drugs are covered by Medicare Part B ("Covered Drugs").

15. In determining the amount it will pay, Medicare calculates the "allowed" amount for the drug. During the period 1992 through 1997, Medicare's reimbursement for Covered Drugs was set at the lesser of the estimated acquisition cost or national average wholesale price. This payment methodology was set forth in 42 C.F.R. § 405.517, a regulation first published in the Federal Register on November 25, 1991 and which became effective on or about January 1, 1992.

16. The estimated acquisition cost for a drug could be determined by the Medicare Program "based on surveys of the actual invoice prices paid for the drug" taking into consideration the estimated acquisition cost, including "factors such as inventory, waste and spoilage." However, historically it has been the AWP published in the *Red Book* or other compendia that has been used as a ceiling for Medicare reimbursement.

17. On January 1, 1998, 42 C.F.R. § 405.517 was amended to provide that the allowed amount would be based upon the lower of the billed charge on the Medicare claim form or 95 percent of AWP.

18. The Medicare Program has publicly announced that it would use the AWP published in pharmaceutical industry magazines as the basis for reimbursement. Specifically,

Program Memorandum AB-99-63 (dated September 1999 but re-issuing PM AB-98-76 dated in December 1998), a publicly available Medicare Program bulletin, confirmed that reimbursement for certain Medicare Part B drugs and biologicals "are paid based on the lower of the billed charge or 95 percent of the AWP as reflected in sources such as the *Red Book*, *Blue Book*, or Medi-Span."

19. Pursuant to PM AB-99-63, the AWP for a single-source drug or biological equals the AWP of the single product.

20. Medicare Part B reimburses medical providers 80% of the allowable amount for a drug. The remaining 20% is paid by the Medicare Part B beneficiary, and is called the "co-payment" amount. All medical providers are required by law to bill the 20% co-payment and make attempts beyond merely billing to collect that amount.

21. In setting reimbursement rates, the Medicare Program uses the AWPs generated by the pharmaceutical industry, as do State Medicaid programs. There are no regulations describing how AWPs are to be calculated, nor any regulatory process for approving them. Pharmaceutical companies do not report AWPs directly to the federal government, but instead send their pricing information to independent publishing companies that compile the data and publish the AWPs in trade publications, which are then used by the government, as well as private health plans.

22. The importance of an accurate AWP was recently reconfirmed by the Office of the Inspector General ("OIG") in an April 2003 report: "Compliance Program Guidance for Pharmaceutical Manufacturers." The OIG report found that the "government sets reimbursement with the expectation that the data provided are complete and accurate." The OIG report made it clear that the AWP must be a meaningful figure that is not artificially inflated:

> Where appropriate, manufacturers' reported *prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to*

> ***some or all purchasers***. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements. [Emphasis added.]

23. And, the OIG rejected the notion that purposeful AWP manipulation was a lawful practice:

> The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.
>
> Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.
>
> If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.
>
> In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing

> practices. ***The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute.*** Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product. [Emphasis added.]

2. Procrit and Defendant's Unlawful Acts

24. Defendant Ortho manufactures and markets Procrit® (Epoetin Alfa). According to Ortho's website it is one of Ortho's "most important products."

25. Procrit is used in the treatment of anemia associated with cancer chemotherapy.

26. Procrit is an expensive drug.

27. As set forth below, the Defendant Drug Manufacturer perpetrated the alleged fraudulent scheme by using some and/or all of the following practices:

a. Artificially Inflating AWPs

28. Defendant Ortho provided AWPs for each of its drugs to the *Red Book*, the *Blue Book*, Medi-Span and other pharmaceutical compendia for Covered Drugs and non-Part B drugs, both brand name and generic. This included AWPs for Procrit.

29. Ortho deliberately and intentionally published AWPs for Procrit that did not reflect the actual pricing structure of the drugs, but was created solely to cause overpayment for Procrit by Medicare and Medicaid. Ortho created and perpetuated this scheme so that the medical providers who purchased these drugs at a low cost would bill Medicare and Medicaid at the inflated AWPs and earn a substantial profit from the "spread" between the real cost and the various AWP-related reimbursement rates.

30. Ortho knew and understood that Medicare and Medicaid used the *Red Book* and other publications to determine the AWPs of the drugs. Because Ortho controlled the AWPs published in the *Red Book* and other compendia, Ortho knew and understood that it could

manipulate the providers' profits. The purpose of artificially inflating the providers' profits was to create an illegal kickback to the providers, funded by Medicare and Medicaid.

b. **Improper Use of Free Samples**

31. Defendant Ortho, through its sales personnel and marketing representatives, also provided free samples of its drugs to providers as a means of lowering the price. The free samples were used to offset the total cost associated with the purchases of the drugs, thereby increasing the "spread." Moreover, Ortho specifically told providers to bill patients for the free samples, which Ortho knew was unlawful.

32. Every free sample of a drug for which a provider bills a patient or insurer effectively reduces that provider's overall cost for that drug. However, the full cost of the Covered Drug Procrit was charged to Medicare and Medicaid, and the free sample is not used by the drug company in calculating the AWP, which in turn inflates the AWP.

33. Although Ortho provided free samples and marketed them as a way to lower the providers' actual cost of Procrit, they did not include the value of the free samples in calculating the AWP for Procrit. Thus, Ortho effectively and improperly passed on the cost of the free samples directly to Medicare and Medicaid.

c. **Other Hidden and Improper Inducements and Price Reductions**

34. Ortho has provided and/or arranged for many other non-public financial inducements to stimulate sales of Procrit at the expense of Medicare. Such inducements included volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and educational and promotional grants. All of these incentives were designed to lower the providers' net cost of purchasing Procrit. And again, the value of these services was kept "off the book," so as to not be reflected in the AWP, which in turn inflates the AWP.

d. Specific Examples of Abuse

35. Mark E. Duxbury was employed as a sales person by Ortho Biotech from February 11, 1992 through July 20, 1998. His job titles ranged from Product Specialist to Regional Key Account Specialist. Mr. Duxbury won the 1993 and 1994 Biosphere awards, Ortho Biotech's top national annual sales award which is given to the top ten percent of their sales force for Procrit sales achievements. Although Mr. Duxbury questioned the legality of Ortho Biotech's marketing practices, he was assured that management's directives and strategies were legal.

36. Ortho Biotech purchases and sells its Procrit™ brand of Epoetin alfa from Amgen, Inc. under an agreement known as the Procrit Marketing License Agreement ("the Marketing Agreement"). Epoetin alfa is a growth factor for red blood cells and is used to treat severe anemia.

37. The Food and Drug Administration requires that each product carry indications ***for all approved uses*** in its Package Insert because the two brands are identical in every way, except the label. For example, Ortho and Johnson & Johnson are prohibited from marketing Procrit for dialysis use, but its Package Insert carries the indication for dialysis. In addition, Medicare acknowledges no difference between the two products and ***will reimburse for both brands*** when they are used to treat dialysis patients in the End Stage Renal Disease ("E.S.R.D.") program under Medicare Part B.

(1) Free Commercially Packaged Drug and Rebates

38. During the time of relator's employment, Ortho offered substantial discounts, rebates, unrestricted educational grants, and free commercially packaged Procrit to dialysis customers in order to create a lower effective net purchase price and a greater profit spread from the inflated AWP reported to Medispan, *Red Book*, and other publishers. Ortho Biotech used surrogate companies, Charise Charles, Lt. and MarketCheck, Inc., to facilitate these schemes. The surrogate companies would use the U.S. mail to send rebates to dialysis clinics throughout

the country. These rebates were hidden from Medicare and were not accounted for in calculating defendant's report AWP for Procrit.

39. Defendants also offered substantial quantities of free Procrit. Much of the free commercially packaged Procrit was ultimately billed to Medicare. Free commercially packaged Procrit can be identified and quantified easily by obtaining copies of Ortho Biotech's "Patient Trial Cards." These are sequentially numbered documents which identify the physician who received the drug and the representative who provided the drug. Identifying physicians who fraudulently billed Medicare for free Procrit is simple and may be obtained in two ways: (1) If the physician administered the free product to a patient, the physician's office would have billed Medicare for the injection fee, but no drug; (2) A comparison may be made between the volume of Procrit purchased by the physician and the amount of Procrit billed to Medicare. There were thousands of "Patient Trial Cards" provided to sales representatives, each of which was worth well over $1,000 in free Procrit. One Ortho Biotech sales representative, Mr. Dean McClellan, had over 400 Patient Trial Cards in his possession at one time. Based upon his experience at the company, relator believes that this practice was common throughout the country. Medicare was billed for free Procrit and the free Procrit was not accounted or in calculating AWPs.

(2) **Phony Drug Studies**

40. Another method of inflating reimbursement for use of Procrit was through Phase IV Clinical Trials. Phase IV Trials are defined by the FDA as a method of evaluating a drug in a "real world" clinical setting. Ortho Biotech extensively used Phase IV Marketing Trials as a way to accomplish a number of marketing goals:

a) To provide cash payments to a physician, clinic or hospital which lowers the effective net acquisition cost of the drug. This allows the manufacturer to provide a lower "best price" to physicians than what it reports to the Federal Government, resulting in inflated Medicaid payments for the drug.

b) To provide cash payments to a physician, clinic or hospital to influence the physician to use more of the drug in practice.

c) To provide cash payments in order to encourage the physician, clinic or hospital to use the drug in a way which is inconsistent with its FDA approved indications and administration methods. In 1997, Ortho Biotech launched a massive Phase IV Marketing Trial which paid physicians to dose Procrit at 40,000iu in a once per week dose instead of the FDA approved dosage of 10,000iu three times per week dosage in cancer-chemotherapy patients. The trial was very successful and the once per week dosage is now universally accepted among oncologists. ***The trial's success also resulted in Medicare Part B paying for 40,000iu/week of Procrit in cancer chemotherapy patients instead of 30,000iu/week – an increase of 33% in payments for each Medicare Beneficiary receiving Procrit for treatment of their chemotherapy related anemia.***

41. The approved dosage by the FDA is 10,000iu three times a week. By dosing at 40,000 units once a week, Ortho increases the provider's take, but in doing so, intentionally has established a practice whereby Medicare pays more than the approved FDA dosage. The 40,000iu dosage scheme was successful for Ortho and doctors, but Ortho has ***not*** received FDA approval for such dosage. Thousands of patients have been treated with this dosage. In 1997, Medicare was spending close to $1 billion for EPO.

42. Ortho Biotech's Phase IV Trials also provided thousands of dollars worth of free commercially packaged Procrit to the participating physicians, clinics or hospitals which were billed to Medicare. Again, a simple audit of the account's purchases of Procrit around the time of the trial period and comparison to the amount of Procrit billed to Medicare will identify fraudulent billing practices.

(3) Unrestricted Educational Grants

43. In order to convert a hospital with a large dialysis center to Procrit, defendant provided unrestricted educational grants totaling $40,000 during an 18-month period beginning in the spring of 1993. The account was St. Joseph's Hospital in Tacoma Washington. The grants substantially reduced the effective net acquisition price (which was already 15% below

AWP) for Procrit and were not used by Ortho in reporting its AWP. Plaintiff is aware that this was a common practice Ortho used to obtain market share.

44. Ortho Biotech maintains large pools of money to be disbursed as Unrestricted Educational Grants which are believed to be now called the S.A.F.E. program. Each Unrestricted Educational Grant requires a written request from the sales representative to his/her manager and includes a description of what benefit to Ortho Biotech is expected in return for the grant. The fact that Ortho Biotech uses these grants to buy influence with physicians and hospitals will be obvious once the grant request forms are made available to investigators.

V. VIOLATIONS OF LAW

45. At all times material to this Complaint, it was a violation of Title 42 U.S.C. § 1320a-7b(1) and (b)(2), for an employee of a company engaged in the lawful distribution of drugs to knowingly and willfully offer and pay any remuneration, including any kickback, bribe or rebate, directly or indirectly, covertly or overtly, in cash or in kind, to anyone to induce that person to order or to recommend the ordering of any drug for which payment was made in whole or in part by the Medicare of Medicaid Programs, or, after 1996, by any other federal health care program. At all times material to this Complaint, defendant was aware of and approved the promotion of Procrit in this fashion.

46. At all times material to this Complaint, the Prescription Drug Marketing Act provided in part as follows:

a. Title 21 United States Code § 331(t) prohibited the sale, purchase and trade, and the offer to sell, purchase and trade, drug samples in violation of § 353(c) of that Act. Section 331(t) also prohibited causing such conduct.

b. Section 353(c) provided that no person may sell, purchase or trade or offer to sell, purchase or trade any drug sample. Section 353(c)(1) applied to samples of a drug which was intended for human use but, because of its toxicity, potential for harmful effect and method of use, and the collateral measure necessary for use, was not safe for use except under the

supervision of a practitioner licensed by law to administer such drug and with written prescription of such practitioner. Section 353(c)(1) further provided that a sample of such a drug was a unit of drug not intended to be sold but intended to promote the sale of the drug. Procrit is a drug subject to the requirements of § 353(c)(1) and the free samples of the drug Procrit provided to physicians by sales representatives were drug samples within the meaning of § 353(c)(1), and were provided with the intent that they be sold by the practitioner.

c. Section 353(c)(3) permitted a manufacturer of a drug to distribute samples of the drug through its sales representatives but only if a practitioner licensed to prescribe the drug made a written request for such samples, which request contained at least the following: the name, address and professional designation of the practitioner, the identity and quantity of the drug requested, the name of the manufacturer of the drug, the date of the request, and the practitioner's signature.

VI. COUNTS

COUNT I

SUBSTANTIVE VIOLATIONS OF THE FALSE CLAIMS ACT (31 U.S.C. §§ 3729(a)(1), (a)(2), (a)(7) and 3732(b))

47. Relator realleges and incorporates by reference the preceding allegations.

48. This is a claim for treble damages and forfeitures under the False Claims Act, 31 U.S.C. §§ 3729-32, as amended.

49. By publishing inflated AWPs for Procrit that did not (a) represent a real average of wholesale prices and (b) failed to account for free samples, educational grants and rebates, defendant knowingly caused to be made a false or fraudulent claims to be paid for by the government. It was not only foreseeable but it was intended that physicians would submit a false claim for reimbursement.

50. Through the acts described above, defendant and its agents and employees knowingly presented and caused to be presented to the United States government and state

governments participating in the Medicaid program, false and fraudulent claims, records, and statements in order to obtain reimbursement for health care services provided under Medicare and Medicaid.

51. Through the acts described above and otherwise, defendant and its agents and employees knowingly made, used, and/or caused to be made or used false records and statements in order to get such false and fraudulent claims paid and approved by the United States government.

52. Through the acts described above and otherwise, defendant and its agents and employees knowingly made, used, and caused to be made or used false records and statements to conceal, avoid, and/or decrease defendant's obligation to repay money to the United States government that defendant improperly and/or fraudulently received. Defendant also failed to disclose to the Government material facts that would have resulted in substantial repayments by it to the federal and state governments.

53. The United States, its fiscal intermediaries, and the state Medicaid programs, unaware of the falsity of the records, statements, and claims made or submitted by defendant and its agents and employees paid and continue to pay defendant for claims that would not be paid if the truth were known.

54. The United States, its fiscal intermediaries, and the state Medicaid programs, unaware of the falsity of the records, statements, and claims made or submitted by defendant – or of its failure to disclose material facts which would have reduced government obligations – have not recovered Medicare, Medicaid, and CHAMPUS funds that would have been recovered otherwise.

55. By reason of the defendant's false records, statements, claims, and omissions, the United States and the state Medicaid programs have been damaged in the amount of many millions of dollars in Medicare and Medicaid funds.

COUNT II

(FALSE CLAIMS ACT CONSPIRACY (31 U.S.C. § 3729(a)(3) AND 3732(b))

56. Relator realleges and incorporates by reference the preceding allegations.

57. This is a claim for treble damages and for forfeitures under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, as amended.

58. Through the acts described above and otherwise, defendant entered into a conspiracy or conspiracies among itself and with others to defraud the United States and state Medicaid programs by getting false and fraudulent claims allowed or paid. Defendant has also conspired to omit disclosing or to actively concealing facts which, if known, would have reduced government obligations to Ortho or resulted in repayments from it to government programs. Defendant has taken substantial steps in furtherance of those conspiracies, *inter alia*, by preparing false cost reports and other records, by submitting such records to the Government for payment or approval, and by directing its agents, consultants, and personnel not to disclose and/or to conceal defendant's fraudulent practices.

59. The United States, its fiscal intermediaries, and state Medicaid programs, unaware of defendant's conspiracies or the falsity of the records, statements and claims made by defendant and its agents, employees and co-conspirators, and as a result thereof, have paid and continue to pay tens of millions of dollars in Medicare and Medicaid reimbursement that they would not otherwise have paid.

60. By reason of defendant's conspiracies and the acts taken in furtherance thereof, the United States and the state Medicaid programs have been damaged in the amount of many tens of millions of dollars in Medicare and Medicaid funds.

VII. PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against defendant as follows:

A. That defendant ceases and desists from violating 31 U.S.C. § 3729 *et seq.*;

B. That the Court enter judgment against defendant in an amount equal to three times the amount of damages the United States has sustained as a result of defendant's actions, as well as a civil penalty against defendant of $10,000 for each violation of 31 U.S.C. § 3729;

C. That Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the Federal Civil False Claims act;

D. That Relator be awarded all costs and expenses of this action, including attorneys' fees; and

E. That the United States and Relator receive all such other relief as the Court deems just and proper.

VIII. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

DATED: November 6, 2003.

HAGENS BERMAN LLP

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